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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/552,953 | 05/25/2006 | Richard D. Shunnarah | 55142.010102 | 2493 |
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| GREENBERG TRAURIG, LLP MET LIFE BUILDING | | | MARTIN, PAUL C | |
| 200 PARK AVENUE NEW YORK, NY 10166 | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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SchindlerB@gtlaw.com LucasCh@gtlaw.com NYIPmail@gtlaw.com

| ## Diffice Action Summary The MAILING DATE of this communication appears on the cover sheet with the correspondence address | · · | Application No. | Applicant(s) | | | | |
|--|---|---|--|--|--|--|--|
| ### Deficies Action Summary Examiner | | 10/552,953 | SHUNNARAH ET AL. | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address − Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Edentions of the map be available under that provides of 37 CFR 1.180, in no event, however, may a reply be timely filed as the control of the maintain statutory period wite apply and wite spins SIX (8) MONTHS from the mailing date of this communication. Plante to reply within the set or sended period for eyely a specified above, the maintain statutory period wite apply and wite spins SIX (8) MONTHS from the mailing date of this communication. Plante to reply within the set or sended period for eyely with by statute, cause the application to be some ARAMONDOF, 36 U.S. C. § 1335. Any purply received shery the office later than three months after the mailing date of this communication, even if timely filed. The control of this communication (s) filed on | Office Action Summary | | Art Unit | | | | |
| Period for Reply A SHORTEND STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.130(a), in no event, however, may a neigh be timinly filled the provisions of 37 CFR 1.130(a), in no event, however, may a neigh be timinly filled the provisions of 18 CFR 1.130(a). In no event, however, may a neigh be timinly filled the provision of the pro | | Paul C. Martin | 1657 | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of two may be available under the procession of 37 CPR 1.108(), in the event, foreward, may any by be limby find in 18 NO pendo for rap by a specified above, the maximum statutory period will apply and will expire SIX (8) MONTHS from the maining date of this communication. Planto to fine by which the set or contraded pendo for reply will by testing contraded pendo for reply will be set or contraded pendo for reply will be set or contraded pendo for reply. It by statuto, cause the application of 23 U.S.C. § 1313. Any reply received by the Office later than three months after the maxing date of this communication, even if timely fleed, may reduce any seneral particular time adjustment. Set 37 CPR 1.704(s) Status 1) | ··· | | | | | | |
| WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of side may be subtible under the proximise of 37 CFR 11306, in no event, holds, in the side of the sommunication. Failure to reply within the set or extended period for reply will, by studies, cause the application between 8ABAONED (38 U S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication. Failure to reply within the set or extended period for reply will, by studies, cause the application to become 8ABAONED (38 U S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filled, may reduce any earned patient term dejunitement. Status 1) | • • | | | | | | |
| 1) Responsive to communication(s) filed on | WHICHEVER IS LONGER, FROM THE MAILING DA Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing | ATE OF THIS COMMUNICATIO 36(a). In no event, however, may a reply be to will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONI | N. mely filed n the mailing date of this communication. ED (35 U.S.C. § 133). | | | | |
| 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1,3.7-12.15 and 16 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1,3.7-12.15 and 16 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | Status | | | | | | |
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DETAILED ACTION

Claims 1, 3, 7-12, 15 and 16 are pending in this application.

Claim 5 has been omitted from the newly amended claims and is presumed canceled. A new claim set indicating the status of all the claims should be submitted.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3, 7 and 8, drawn to a test element for determining the level of phenylalanine in a biological fluid.

Group II, claim(s) 11, 12 and 16, drawn to a medical device adapted for the monitoring of blood levels of phenylalanine.

Group III, claim(s) 15, drawn to a method of determining the presence or absence of phenylalanine in a biological sample.

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The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The corresponding technical feature, a test element for determining the level of phenylalanine in a biological fluid comprising a layer onto which a sample is applied and a reagent layer comprising a) an enzyme which converts phenylalanine to phenylpyruvate; b) buffered enzymatic color reagents; and c) a hydrophilic polymer is not deemed to make a contribution over the Prior Art and is therefore not "Special".

Iwata et al. teaches a sensor for determining the level of phenylalanine in a blood sample comprising a layer onto which a sample is applied and a reagent layer containing phenylalanine dehydrogenase, buffered alamar blue and gelatin (Column 9, Lines 34-47).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin Examiner Art Unit 1657

10/25/07

JON WEBER

SUPERVISORY PATENT EXAMINER